Claim Amendments

Claims 1 – 58 (cancelled)

Claim 59 (new). A method comprising administering a therapeutically effective amount of a composition comprising [2-(6-amino-purin-9-yl)-1-methyl-ethoxymethyl]-phosphonic acid diisopropoxycarbonyloxymethyl ester fumarate (tenofovir disoproxil fumarate) and (2*R*, 5*S*, cis)-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one (emtricitabine) to a patient in need of antiviral therapy consisting of anti-HIV therapy.

Claim 60 (new). The method of claim 59 wherein the anti-HIV active ingredients in the composition consist of tenofovir disoproxil fumarate and emtricitabine.

Claim 61 (new). The method of claim 60 wherein the composition comprises about 300 mg of tenofovir disoproxil fumarate and about 200 mg of emtricitabine.

Claim 62 (new). The method of claim 59 wherein the amount of the total tenofovir disoproxil fumarate and emtricitabine in the composition in relation to carrier material is about 5% to about 95% of the total composition (weight:weight, exclusive of coating).

Claim 63 (new). The method of claim 59 wherein tenofovir disoproxil fumarate and emtricitabine are present in a tablet.

Claim 64 (new). The method of claim 63 wherein tenofovir disoproxil fumarate and emtricitabine are present in an amount of 300 mg and 200 mg respectively.

Claim 65 (new). The method of claim 59 wherein the manufacture is by wet granulation.

Claim 66 (new). The method of claim 62 wherein the weight ratio of the total of tenofovir disoproxil fumarate and emtricitabine in the composition in relation to ingredients other than tenofovir disoproxil fumarate and emtricitabine is 50:50 (excluding coating).

Claim 67 (new). The method of claim 66 wherein the composition comprises in weight percent (excluding coating) tenofovir disoproxil fumarate 30, emtricitabine 20, pregelatinized starch 5, croscarmellose sodium 6, lactose monohydrate 8, microcrystalline cellulose 30, magnesium stearate 1.

Claim 68 (new). The method according to claim 59 wherein the composition further comprises a third active ingredient selected from an HIV protease inhibitor (PI), an HIV nucleoside reverse transcriptase inhibitor (NRTI), an HIV non- nucleoside reverse transcriptase inhibitor (NNRTI), and an HIV integrase inhibitor.

Claim 69 (new). The method according to claim 68 wherein the third active ingredient is selected from the Reyataz, Kaletra, or Sustiva anti-HIV agents.

Claim 70 (new). The method according to claim 59 wherein the composition further comprises a pharmaceutically acceptable glidant.

Claim 71 (new). The method according to claim 70 wherein the glidant is selected from silicon dioxide, powdered cellulose, microcrystalline cellulose, metallic

stearates, sodium aluminosilicate, sodium benzoate, calcium carbonate, calcium silicate, corn starch, magnesium carbonate, asbestos free talc, stearowet C, starch, starch 1500, magnesium lauryl sulfate, magnesium oxide, and formulations thereof.

Claim 72 (new). The method according to claim 71 wherein the metallic stearates are selected from calcium stearate, magnesium stearate, zinc stearate, and formulations thereof.

Claim 73 (new). A pharmaceutical formulation comprising [2-(6-amino-purin-9-yl)-1-methyl-ethoxymethyl]-phosphonic acid diisopropoxycarbonyloxymethyl ester fumarate (tenofovir disoproxil fumarate) and (2*R*, 5*S*, cis)-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one (emtricitabine).

Claim 74 (new). The pharmaceutical formulation according to claim 73 further comprising one or more pharmaceutically acceptable carriers or excipients.

Claim 75 (new). The pharmaceutical formulation according to claim 74 wherein the pharmaceutically acceptable carriers or excipients are selected from pregelatinized starch, croscarmellose sodium, povidone, lactose monohydrate, microcrystalline cellulose, and magnesium stearate, and formulations thereof.

Claim 76 (new). The pharmaceutical formulation according to claim 74 wherein the amount of the total tenofovir disoproxil fumarate and emtricitabine in the formulation in relation to carrier and excipient material (weight:weight, excluding coating) is about 5% to about 95% (weight ratio 0.08).

Claim 77 (new). The pharmaceutical formulation according to claim 76 wherein the weight ratio of tenofovir disoproxil fumarate and entricitabine together:

total carrier and excipient in the formulation (excluding coating) is 500:1000, 400:900, 325:825, 225:725, 200:700, 500:700, 500:670, 500:763, 500:2840 or 500:2270.

Claim 78 (new). The pharmaceutical formulation according to claim 77 wherein the weight ratio (excluding coating) is 0.50, 0.44, 0.39, 0.31, 0.29, 0.71, 0.75, 0.65, 0.18 or 0.22.

Claim 79 (new). The pharmaceutical formulation according to claim 76 wherein the weight ratio (excluding coating) is from 0.18 to 0.75.

Claim 80 (new). The pharmaceutical formulation according to claim 73 in pharmaceutical dosage form.

Claim 81 (new). The pharmaceutical formulation according to claim 80 wherein the pharmaceutical dosage form is a tablet.

Claim 82 (new). The pharmaceutical formulation according to claim 73 wherein tenofovir disoproxil fumarate and emtricitabine are present in a ratio of about 300:200 by weight.

Claim 83 (new). The pharmaceutical formulation according to claim 82 comprising about 300 mg of tenofovir disoproxil fumarate and about 200 mg of emtricitabine.

Claim 84 (new). The pharmaceutical formulation according to claim 73 suitable for oral administration.

Claim 85 (new). The pharmaceutical formulation according to claim 84 wherein the pharmaceutical dosage form is a capsule.

Claim 86 (new). The pharmaceutical formulation according to claim 73 suitable for administration once per day to an infected human.

Claim 87 (new). A patient pack comprising (a) at least one coformulated pharmaceutical formulation comprising [2-(6-amino-purin-9-yl)-1-methyl-ethoxymethyl]-phosphonic acid diisopropoxycarbonyloxymethyl ester fumarate (tenofovir disoproxil fumarate) and (2*R*, 5*S*, cis)-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one (emtricitabine), and (b) an information insert containing directions for the use of tenofovir disoproxil fumarate and emtricitabine in formulation for the treatment of a patient in need of antiviral treatment consisting of anti-HIV therapy.

Claim 88 (new). The patient pack according to claim 87 wherein the pharmaceutical dosage form is a tablet, caplet, or capsule comprising 300 mg of tenofovir disoproxil fumarate and 200 mg of emtricitabine.

Claim 89 (new). The pharmaceutical formulation of any of Claims 73 or 87 which further comprises a third antiviral agent.

Claim 90 (new). The formulation of Claim 89 wherein the third agent is selected from an HIV protease inhibitor (PI), an HIV nucleoside reverse transcriptase inhibitor (NRTI), an HIV non- nucleoside reverse transcriptase inhibitor (NNRTI), and an HIV integrase inhibitor.

Claim 91 (new). The formulation of Claim 90 wherein the third antiviral agent is a PI.

Claim 92 (new). The formulation of Claim 90 wherein the third antiviral agent is an NNRTI.

Claim 93 (new). The formulation of Claim 90 wherein the third antiviral agent is selected from the Reyataz, Kaletra, or Sustiva anti-HIV agents.

Claim 94 (new). An oral pharmaceutical dosage form comprising tenofovir disoproxil fumarate, emtricitabine and Reyataz.

Claim 95 (new). An oral pharmaceutical dosage form comprising tenofovir disoproxil fumarate, emtricitabine and Kaletra.

Claim 96 (new). An oral pharmaceutical dosage form comprising tenofovir disoproxil fumarate, emtricitabine and Sustiva.

Claim 97 (new). The pharmaceutical formulation of claim 73 comprising in weight percent (excluding coating) tenofovir disoproxil fumarate 30, emtricitabine 20, pregelatinized starch 5, croscarmellose sodium 6, lactose monohydrate 8, microcrystalline cellulose 30, and magnesium stearate 1.

Claim 98 (new). A tablet comprising 300 mg of tenofovir disoproxil fumarate, 200 mg of emtricitabine and carriers and/or excipients sufficient to produce less than 5% acid degradation of tenofovir disoproxil fumarate or emtricitabine after six months storage with desiccant at 40°C/25% relative humidity.

Claim 99 (new). An oral dosage form comprising Sustiva, 300 mg tenofovir disoproxil fumarate, 200 mg of emtriva and pharmaceutically acceptable carriers or excipients.